MAY 0 6 2002

K020716

510 (k) SUMMARY (21 CFR PART 807.92)

Product

Rapid Opiates Test Strip II, Rapid Opiates Test Card II and DOA Multiple Drug Test Cards (up to six tests).

Name of Manufacturer

Rapid Diagnostics, Inc. 1429 Rollins Road, Burlingame, CA 94010, U.S.A.

Principle

The Rapid Drug tests are based on the principle of specific immunochemical reaction between antibodies and antigens to analyze particular compounds in human urine specimen. The assay relies on the competition for antibody binding between drug conjugate and free drug which may be present in the urine specimen being tested.

When drug is present in the urine specimen, it competes with drug conjugate for the limited amount of antibody-dye conjugate. When the amount of drug is equal or more than the cutoff level, it will prevent the binding of drug conjugate to the antibody. As a result, a positive urine specimen will not show a colored band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result.

Intended Use

The Rapid Drug Tests are immunochromatography based one step *in vitro* test. It is designed for qualitative determination of Amphetamine, Benzodiazepines, Cocaine, Methamphetamine, Opiates, Phencyclidine and THC in human urine specimen above the following cutoff level:

Amphetamine	1000ng/ml
Benzodiazepines	300ng/ml
Cocaine	300ng/ml
Methamphetamine	1000ng/ml
Opiates	300ng/ml
Opiates II	2000ng/ml
Phencyclidine	25ng/ml
THC	50ng/ml

Performance

The studies performed are listed below:

Rapid Opiates Test Strip II
- Sensitivity
- Accuracy (comparison study of clinical urine specimens)
- Stability – Specimen
- Stability – Product
- Precision
- Reproducibility
- Specificity
- Interference

Rapid Opiates Test Card II
- Accuracy (comparison study of clinical urine specimens)
- Precision
- Comparison between Rapid Opiates Test Strip II and Test Card II

Both urine control specimen and clinical urine specimen were tested to evaluate the safety and effectiveness of Rapid Opiates Test Strip II and Rapid Opiates Test Card II. The other component strips, Amphetamine, Benzodiazepine, Cocaine, Methamphetamine, Opiates (at 300ng/ml cutoff), Phencyclidine and THC in Multiple Test Panels have received FDA approval in submission K003809 and K003809/A002.

The results of performance characteristics demonstrate Rapid Opiates Test Strip II and Rapid Test Card II to be substantially equivalent to the Applied Biotech ***SureStep*** ™ **Drug Screen Test Morphine II,** which received 510 (k) approval.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Charles Yu
President/Official FDA Correspondent
Rapid Diagnostics, Inc.
1429 Rollins Road,
Burlingame, CA 94010

MAY 0 6 2002

Re: k020716
Trade/Device Name: Rapid Opiates Test Card II
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG
Dated: February 18, 2002
Received: March 5, 2002

Dear Mr. Charles Yu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510 (K) number (if known): K020716

Device Name: Rapid Opiates Test Card II

Indications for Use:

Rapid Opiates Test Card II is an imunochromatorgraphy based one step *in vitro* test. It is designed for qualitative determination of Opiates and its metabolites in human urine specimens. The presence of Morphine in human urine above a cutoff level of 2,000ng/ml can be detected.

The test kit is used to obtain a visual, qualitative result and is intended for professional use. It is not intended for over the counter sale to lay persons.

Concurrence of the CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020716

Prescription Use: √ OR Over the Counter Use: _____
(Per 21 CFR 801.109)